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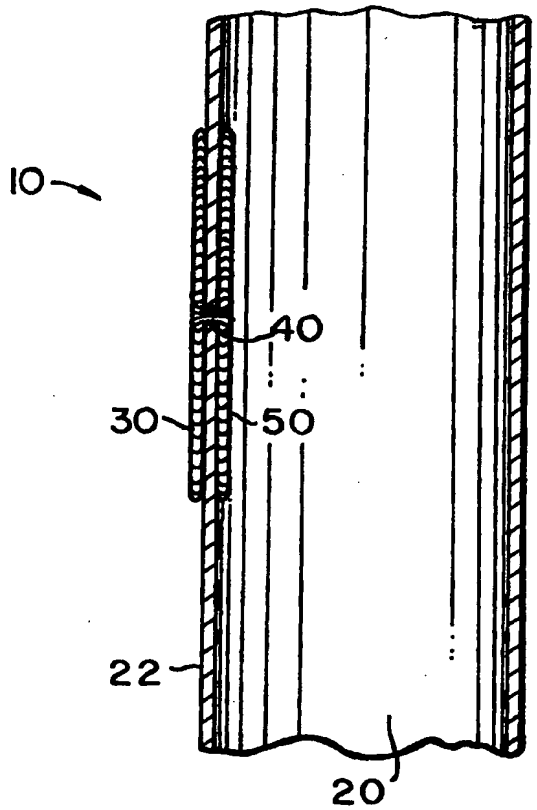
(54) Title: MEDICAL PLUG

(57) Abstract

A medical plug has first and second relatively large end portions joined by a relatively small linking structure. The plug is preferably highly deformable and resilient so that it can be applied by deforming an end portion, passing that deformed end portion through a body tissue hole to be plugged, and then allowing the deformed end portion to resume its original shape. When installed, each end portion of the plug is on a respective opposite side of the body tissue wall having the hole to be plugged, and the linking structure passes through that hole. The plug can be installed intralumenally and/or remotely if desired.



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MEDICAL PLUG

Background of the Invention

This invention relates to medical plugs, and more particularly to medical plugs which can be installed intralumenally if desired. The invention also relates to methods and apparatus for delivering and installing medical plugs, especially intralumenally if desired.

Increasing numbers and types of intralumenal procedures are being performed on medical patients. For example, there are intravascular blood flow measurement procedures, balloon angioplasty procedures, intravascular stent installation procedures, and even intravascular coronary bypass procedures (see, for example, Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, which is hereby incorporated by reference herein). These procedures may involve putting one or more holes in the walls of circulatory system vessels, and it may be necessary to thereafter plug those holes. Some of these holes may be located very remotely from where the medical instrumentation enters the patient's body. Such holes may therefore only be conveniently reachable intravascularly.

The above-mentioned intravascular procedures are only some examples of where plugs may be needed to plug holes in body tissue walls. The side walls of

other tubular body organs may have holes that require plugging, and again it may be desired to deliver a plug to such a hole intralumenally. Any other body tissue wall may also require a plug in a hole, and it may sometimes be necessary to deliver a plug to such a hole remotely and/or with convenient access to only one side of the tissue wall.

In view of the foregoing it is an object of this invention to provide improved medical plugs.

It is a more particular object of this invention to provide medical plugs that can be installed intralumenally and/or remotely if desired.

It is still another object of this invention to provide methods and apparatus for installing medical plugs.

It is yet another object of this invention to provide methods and apparatus for intralumenally and/or remotely installing medical plugs.

It is still another object of this invention to provide methods for making medical plugs.

Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing medical plugs which have two relatively large end portions joined by a relatively small linking structure between the end portions. For example, the end portions may have the shape of two relatively large discs that are substantially parallel to and face one another. The linking structure between the discs has a relatively small cross section parallel to the planes of the discs. The linking structure is preferably connected to each disc near the center of the disc. The plug is installed in a hole in a body tissue wall with one of the end portions (e.g., one of

the discs) on one side of the wall, with the other end portion (e.g., the other disc) on the other side of the wall, and with the linking structure passing through the hole. The end portions are preferably close enough to one another that they each bear on the adjacent body tissue wall surface. The plug preferably provides a fluid-tight seal of the hole in which it is installed.

A preferred construction of a plug of this invention includes an open framework of a first highly elastic material. For example, this framework may be a mesh made of nitinol. The framework is covered with a preferably continuous web of a second highly elastic material such as silicone.

A preferred method of installing a plug in accordance with this invention includes deforming the plug into a tubular shape that has a longitudinal axis substantially parallel to an axis passing through the linking structure between the two end portions in the undeformed plug. The tubular shape is then caused to pass axially part way through the hole to be plugged. The tubular shape is then released so that it can return to its undeformed shape with each end portion on a respective side of the body tissue wall that has the hole and with the linking structure passing through the hole between the end portions.

Apparatus for installing a plug in accordance with the above-described method may include a tubular mandrel around which the plug can be deformed into the above-mentioned tubular shape. A releasable retainer mechanism is used to releasably hold the plug on the mandrel in the deformed tubular shape. The mandrel and the tubularly deformed plug are inserted axially into the hole to be plugged. For example, this may be done intralumenally by extending the mandrel through a catheter tube in a blood vessel or other tubular body

organ. The releasable retainer mechanism is then operated to release the plug from the mandrel as the mandrel is withdrawn from the hole. As the plug is released from the mandrel it returns to its undeformed shape and is left in the hole.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

Brief Description of the Drawings

FIG. 1 is a perspective view of an illustrative embodiment of a medical plug constructed in accordance with this invention.

FIG. 2 is an elevational view, partly in section, of the plug of FIG. 1 installed in a hole in the wall of a patient's tubular body organ.

FIG. 3 is a simplified perspective view of illustrative apparatus for installing the plug of FIGS. 1 and 2 in accordance with the invention.

Detailed Description of the Preferred Embodiments

An illustrative plug 10 constructed in accordance with the invention is shown in FIGS. 1 and 2. FIG. 1 shows plug 10 by itself, while FIG. 2 shows plug 10 installed in a hole in a wall 22 of a patient's tubular body organ 20. For example, organ 20 may be the patient's aorta.

Plug 10 has two relatively large end portions 30 and 50 in the shape of hollow discs that are held together by a relatively small, intermediate linking structure 40. Discs 30 and 50 are preferably substantially parallel to one another and close together. Linking structure 40 is preferably disposed

at the center of each disc 30 and 50. Although plug 10 may be made in any of a wide range of sizes, in an illustrative embodiment each of discs 30 and 50 is about 0.350 inches in diameter and about 0.035 inches thick. The cross section of linking structure 40 parallel to discs 30 and 50 is preferably about 0.030 to about 0.060 inches. And the spacing between discs 30 and 50 (in the absence of any intervening body tissue) is preferably as small as possible (most preferably about 0.0 inches).

Plug 10 is preferably made from an open framework 12 of a first highly elastic material covered with a substantially continuous web 14 of a second highly elastic material. For example, framework 12 may be made of nitinol metal and web 14 may be made of silicone. An illustrative technique for making plug 10 is to braid 0.002 to 0.003 inch nitinol wire on a 0.350 inch diameter rod. (The dimensions given herein are only illustrative and will vary depending on the desired size of plug 10.) The resulting nitinol wire mesh is then placed on two forming structures having the shape and approximate relative locations of finished plug discs 30 and 50. These two forming structures are then rotated relative to one another about a central longitudinal axis extending between them to tightly twist the portion of the nitinol wire mesh between them. The wire mesh is then treated (e.g., with heat) to cause it to set in the shape that it has on the forming members (with the tight twist between). The forming members are then removed and the resulting framework 12 is coated with silicone to produce substantially continuous web 14 on the framework.

In use as shown, for example, in FIG. 2, linking structure 40 passes through the hole in the

body tissue wall that is to be plugged. Disc 30 is on one side of that wall, and disc 50 is on the other side of that wall. Linking structure 40 preferably substantially fills the hole to be plugged. The above-mentioned tight twist of linking structure 40 substantially prevents body fluid flow through the linking structure. Discs 30 and 50 hold linking structure 40 in place and cooperate with the linking structure to hold one another in place. Discs 30 and 50 bear resiliently on the opposite sides of the body tissue wall to help prevent body fluid flow around linking structure 40. The entire plug is preferably highly resilient to minimize tissue trauma and to enhance bio-acceptability.

Illustrative apparatus 100 for applying a plug like plug 10 is shown in FIG. 3. The following description of apparatus 100 and of illustrative use of that apparatus will also constitute a description of illustrative methods of applying a plug like plug 10.

As shown in FIG. 3 illustrative apparatus 100 includes a tubular mandrel 110. Plug 10 is deformed into a substantially tubular shape by placing it on the distal end of mandrel 110. For example, if the diameter of the earlier-mentioned rod on which the framework 12 of plug 10 was initially formed was 0.350 inches, the diameter of mandrel 110 may be about 0.085 inches.

Plug 10 may have several features not previously mentioned that cooperate with mandrel 110 and related apparatus. One of these features may be a closed or substantially closed end 32 shown on the left in FIG. 3. At end 32 the members of framework 12 come together or substantially together, and web 14 may be continuous or substantially continuous over that end. An exception may be made for a small hole or

perforation in end 32 if the plug and associated apparatus like 110 are to be inserted via a guidewire (not shown but extremely well known in such procedures as intravascular catheter therapy). End 32 remains distal at the distal end of tube 110. Another feature that plug 10 may have is a relatively strong ring or band 52 as part of its framework 12 at the end of the plug remote from end 32. Band 52 may be formed by massing together and fusing strands of framework 12. Band 52 tends to retain its shape (e.g., 0.085 inch diameter) through all deformations of the remainder of plug 10.

Plug 10 is releasably held on the distal end of tube 110 by a releasable retainer mechanism 120. In the illustrative embodiment shown in FIG. 3, mechanism 120 is a loop of wire 122 that extends distally through tube 110, then out through an aperture 112 in the side of tube 110 proximal of plug 10, and then around band 52. Wire 122 is preferably one continuous length between two ends that are both initially outside the proximal portion of tube 110 and also outside the patient. The distal loop of wire 122 through band 52 exerts a proximally directed force on plug 10 in order to retain the plug on the distal end of tube 110 as shown in FIG. 3.

In the condition shown in FIG. 3 plug 10 may be delivered to the body tissue hole to be plugged via delivery tube 130. For example, if plug 10 is to be applied intralumenally, tube 130 may extend along the interior of a tubular body organ. The distal end of tube 130 may initially extend a short way through the hole to be plugged. Tube 110 with plug 10 on its distal end as shown in FIG. 3 is moved distally through tube 130 until the distal portion of plug 10 is beyond the distal end of tube 130 and through the hole to be

plugged. Plug 10 is then gradually released from tube 110 by allowing the loop of wire 122 to move distally. This allows plug 10, which is trying to resume the shape shown in FIGS. 1 and 2, to begin to move distally relative to tube 110.

The first part of plug 10 to resume its FIGS. 1 and 2 shape is disc 30. Thus disc 30 forms outside the body organ tube having the hole to be plugged. When disc 30 has re-formed, tubes 130 and 110 can be pulled back to withdraw tube 130 from the hole to be plugged and to help snug disc 30 up against the outer surface of the body organ tube wall. Further withdrawal of tubes 130 and 110 and further slackening of wire 122 allows plug 10 to come completely off tube 110 and to return completely to the shape shown in FIGS. 1 and 2. In particular, disc 50 re-forms inside the body organ tube, and linking structure 40 resumes its tightly twisted condition through the hole to be plugged. Plug 10 is now fully installed as shown in FIG. 2 and can be completely released from wire 122 by releasing one end of the wire and pulling the wire out of the patient starting from the other end. Tubes 110 and 130 can also be withdrawn from the patient.

It should be noted that installation of plug 10 is reversible until the plug is released from wire 122. For example, if after disc 30 has been allowed to re-form, the position of the plug is not satisfactory, wire 122 can be retightened to pull plug 10 back onto tube 110 as shown in FIG. 3.

If desired, plug 10 and/or any of its installation apparatus such as tube 110 and/or tube 130 can be provided with radiologic components to permit radiologic observation of the plug and its installation. As just one example, tube 110 and/or tube 130 can be provided with radio-opaque bands. As

another example, band 52 on plug 10 can be made radio-opaque. As still another example, as discs 30 and 50 re-form during installation of the plug, those portions of the plug tend to become denser and therefore more radiologically (e.g., fluoroscopically) visible.

Although band 52 is shown and described as remaining open at substantially all times, band 52 could be constructed (e.g., of nitinol) to close down when not stretched around tube 110. Band 52 could be made of plastic or steel. The apparatus shown in FIG. 3 could be deployed along a central guidewire (e.g., through tube 110 and out via an aperture or perforation in end 32) if desired and as has been mentioned earlier. Tube 130 may not be necessary in all cases and can be omitted if not needed. Intralumenal application of plug 10 has been mentioned above, but the plug 10 can alternatively be applied in other ways such as from the outside of a vessel or other body organ tissue wall requiring a plug.

It will be understood that the foregoing is only illustrative of the principles of this invention and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the framework 12 of the plug can be formed in any of many different ways such as by cutting apertures in an initially imperforate structure; forming a mesh of strands of framework material; braiding, knitting, weaving, or felting together strands of framework material; etc. As has been said, the framework material is preferably an elastic material. Preferred materials are metal, although polymeric materials may also be used. The presently most preferred material is nitinol, and the presently most preferred structure for the framework is a braid of nitinol wires.

The covering 14 on framework 12 is also preferably an elastic, rubber-like material. The covering may be inside the framework, outside the framework, or both inside and outside the framework. The framework is preferably at least partly embedded in the covering. Preferred rubber-like materials for the covering are polymeric materials, especially polymeric rubber materials. The presently most preferred rubber-like material is silicone. Examples of other suitable rubber-like materials are stretchable urethane, stretchable PTFE, natural rubber, and the like. For some applications it may be desirable to make the covering porous. Other applications may not benefit from such porosity. Thus the covering can be either porous or non-porous as desired. Illustrative porosities and techniques for producing porosity are described in the above-mentioned Goldsteen et al. reference in the context of artificial graft structures which can have coverings similar to the coverings used on the plugs of this invention.

The plug may include one or more coatings over covering 14. The coating(s) may be inside the plug, outside the plug, or both inside and outside the plug. Possible coating materials include bio-compatible materials and/or drugs. Examples include hydrophylic polymers such as hydrophylic polyurethane (to create a lubricious surface), parylene (a polymer commonly used to coat pacemakers), PTFE (which may be deposited from a PTFE vapor using a process that is sometimes called vapor transport), the drug Heparin (a common anti-coagulant), collagen, human cell seeding, etc. One purpose of such a coating may be to give the coated surface a very high degree of bio-compatibility and/or a very high degree of smoothness. Any coatings that are used preferably do not interfere with the

elasticity of the plug. The coating(s) may be applied at any suitable and convenient time during the manufacture of the plug. The coating(s) may be applied using any suitable technique such as dipping, electrostatic spraying, vapor transport, in vitro cell reproduction, etc.

The most preferred plugs of this invention (e.g., those with a framework 12 of braided nitinol wires and a silicone covering 14) are highly elastic. The elastic nature of these plugs allows them to be deployed less invasively (e.g., intravascularly or at least percutaneously). This may avoid or reduce the need for surgical implantation. For example, a plug of this invention can be axially stretched to many times its relaxed length, which greatly reduces its diameter. This facilitates intralumenal delivery of the plug. When released from the delivery apparatus, the plug automatically returns to its relaxed shape, with no ill-effects of any kind from its previous deformation.

In the plugs of this invention that are made with a braided nitinol wire framework 12 and a silicone covering 14, the preferred wire diameter is in the range from about 0.0005 to about 0.01 inches. An especially preferred wire diameter is about 0.002 to about 0.003 inches. The preferred silicone covering thickness is in the range from about 0.00025 to about 0.1 inches.

As another example of modifications within the scope of the invention, the particular shapes shown for the various portions of plug 10 are only illustrative and can be varied if desired. Instead of being round discs, plug portions 30 and/or 50 could be elliptical, polygonal, ovoid, or of any other suitable shape. The particular plug dimensions mentioned herein are also only illustrative, and it will be appreciated

that the plugs of this invention can be made in a wide range of sizes for a variety of medical applications.

The Invention Claimed Is

1. A medical plug comprising:

an axially extending linking structure which has a relatively small cross section substantially perpendicular to its axial extent; and

first and second end structures spaced from one another along the axial extent of said linking structure, each of said end structures having a relatively large cross section substantially perpendicular to the axial extent of said linking structure.

2. The plug defined in claim 1 wherein said first end structure is elastically deformable to a relatively small cross section for passage through a body tissue hole to be plugged.

3. The plug defined in claim 1 comprising:

a framework of a first elastic material; and

a web of a second elastic material on said framework.

4. The plug defined in claim 3 wherein said first elastic material includes nitinol.

5. The plug defined in claim 3 wherein said second elastic material includes silicone.

6. The plug defined in claim 3 wherein said framework includes a mesh of said first elastic material.

7. The plug defined in claim 6 wherein said mesh includes a braid of strands of said first elastic material.

8. The plug defined in claim 1 wherein said first and second end structures are elastically deformable to a relatively small cross section.

9. The plug defined in claim 1 wherein said linking structure is closable to substantially prevent fluid flow through said linking structure.

10. The plug defined in claim 1 wherein said first end structure is substantially hollow.

11. The plug defined in claim 1 wherein said first end structure is elastically deformable to a tubular shape.

12. The plug defined in claim 1 wherein said linking structure and said first and second end structures are elastically deformable to a tube.

13. The plug defined in claim 1 wherein said first end structure includes a disc substantially perpendicular to the axial extent of said linking structure.

14. The plug defined in claim 13 wherein said second end structure includes a disc substantially perpendicular to the axial extent of said linking structure.

15. The plug defined in claim 1 further comprising a radiologic marker.

16. The plug defined in claim 1 further comprising:

an anchor member for use in controlling said plug during installation.

17. The plug defined in claim 16 wherein said anchor member comprises:

a ring substantially concentric with the axial extent of said linking structure.

18. A method of making a medical plug comprising:

forming a tubular framework of a first elastic material;

reducing the cross section of an intermediate portion of said framework which is between first and second axially spaced portions of the framework;

setting said framework as shaped in the preceding step; and

covering said framework with a web of a second elastic material.

19. The method defined in claim 18 further comprising:

rotating said first and second axially spaced portions relative to one another about an axis through said cross section of said intermediate portion prior to setting said framework.

20. The method defined in claim 18 further comprising:

substantially closing an axial end of said framework.

21. The method defined in claim 18 further comprising:

forming an annular ring attached to said framework.

22. The method defined in claim 21 wherein said setting comprises:

heating said framework.

23. The method defined in claim 18 wherein said forming comprises:

braiding strands of said first elastic material.

24. The method defined in claim 18 wherein said first elastic material includes nitinol.

25. The method defined in claim 18 wherein said second elastic material includes silicone.

26. The method defined in claim 21 wherein said ring comprises a radiologic marker.

27. A method of installing an elastic plug in a hole through a body tissue wall, the plug including a tubular linking structure of relatively small cross section between first and second hollow end sections of relatively large cross section, said method comprising:

elastically deforming said plug into an elongated tube of relatively small cross section;

inserting said tube axially part way through said hole so that a portion of said tube associated with each of said first and second end

sections is on a respective opposite side of said wall; and

releasing said plug from said elastic deforming.

28. The method defined in claim 27 wherein said wall is a side wall of a tubular body conduit, and wherein said plug is installed with said first end section outside said conduit and said second end section inside said conduit.

29. The method defined in claim 28 wherein said plug is delivered to said hole by passing said plug along the lumen of said conduit while said plug is deformed into said tube.

30. The method defined in claim 27 wherein said elastically deforming comprises:

disposing said plug over a cylindrical surface so that said plug deforms into said tube concentrically with said cylindrical surface

31. The method defined in claim 30 wherein said elastically deforming further comprises:

releasably retaining said plug on said cylindrical surface.

32. The method defined in claim 30 wherein said inserting comprises:

inserting said cylindrical surface axially part way through said hole in order to insert said plug on said cylindrical surface part way through said hole.

33. The method defined in claim 31 wherein said releasing comprises:

undoing said releasably retaining in order to allow said plug to move axially off said cylindrical surface.

34. The method defined in claim 27 wherein said hole is initially penetrated by a tubular member, and wherein said inserting comprises:

passing said plug axially along said tubular member while said plug is deformed into said tube.

35. The method defined in claim 34 wherein said releasing is performed gradually and comprises:

releasing said first end section from said elastic deforming when said first end section is beyond the end of said tubular member which initially penetrates said hole:

removing said tubular member from said hole; and

releasing said second end section from said elastic deforming.

36. Apparatus for installing an elastic plug in a hole through a body tissue wall, the plug including a tubular linking structure of relatively small cross section between first and second hollow end sections of relatively large cross section, said apparatus comprising:

a cylindrical surface over which said plug can be elastically deformed into a tube substantially concentric with said surface; and

a releasable retainer for releasably retaining said plug on said surface.

37. The apparatus defined in claim 36 wherein said releasable retainer comprises:

a longitudinal member forming a loop which engages said plug.

38. The apparatus defined in claim 37 wherein said loop is axially extendable relative to said surface to gradually release said plug from said surface.

39. The apparatus defined in claim 38 wherein said loop is axially retractable relative to said surface to pull said plug back onto said surface.

40. The apparatus defined in claim 37 wherein an end of said longitudinal member is releasable so that said longitudinal member can be pulled from another end completely out of engagement with said plug.

41. The apparatus defined in claim 36 further comprising:

a tubular member disposed concentrically around said plug on said cylindrical surface, said cylindrical surface and said plug being movable axially along said cylindrical member.

42. The apparatus defined in claim 41 wherein said hole is in a side wall of a tubular body organ, and wherein said tubular member is insertable axially into and along the lumen in said tubular body organ in order to deliver said plug to said hole intralumenally.

43. The apparatus defined in claim 42 wherein a distal end portion of said tubular member initially passes through said hole.

44. A medical plug comprising:

a framework of a first elastic material; and

a web of a second elastic material on said framework.

45. The plug defined in claim 44 wherein said first elastic material includes nitinol.

46. The plug defined in claim 44 wherein said second elastic material includes silicone.

47. The plug defined in claim 45 wherein said second elastic material includes silicone.

48. The plug defined in claim 44 having a longitudinal axis along which different axial portions of said plug have cross sections of different sizes.

49. The plug defined in claim 48 wherein said different axial portions are elastically deformable to cross sections of a substantially common size.

50. The plug defined in claim 49 wherein said different axial portions form a tube when elastically deformed to said cross sections of a substantially common size.

51. The plug defined in claim 48 wherein said different axial portions include:

a first portion having a first relatively large cross section;

a second portion having a second relatively large cross section; and

a third portion intermediate said first and second portions and having a third relatively small cross section.

52. The plug defined in claim 51 wherein said intermediate portion is resiliently biased to close to substantially prevent fluid flow through said intermediate portion substantially parallel to said longitudinal axis.

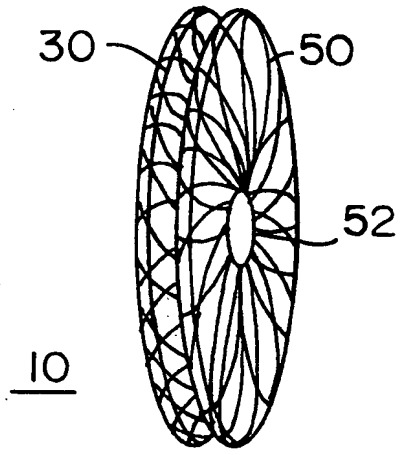

FIG.1

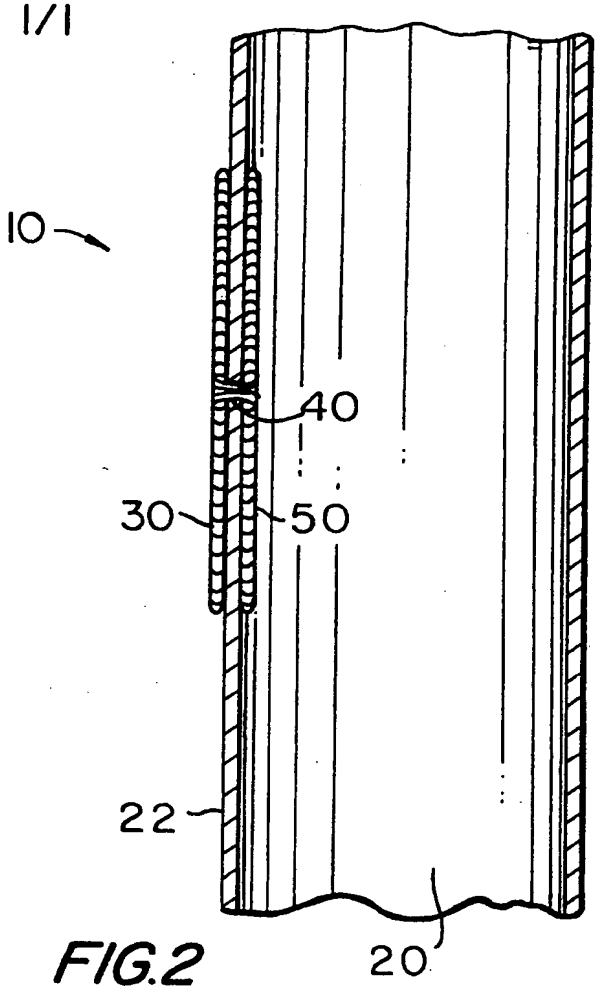

FIG.2

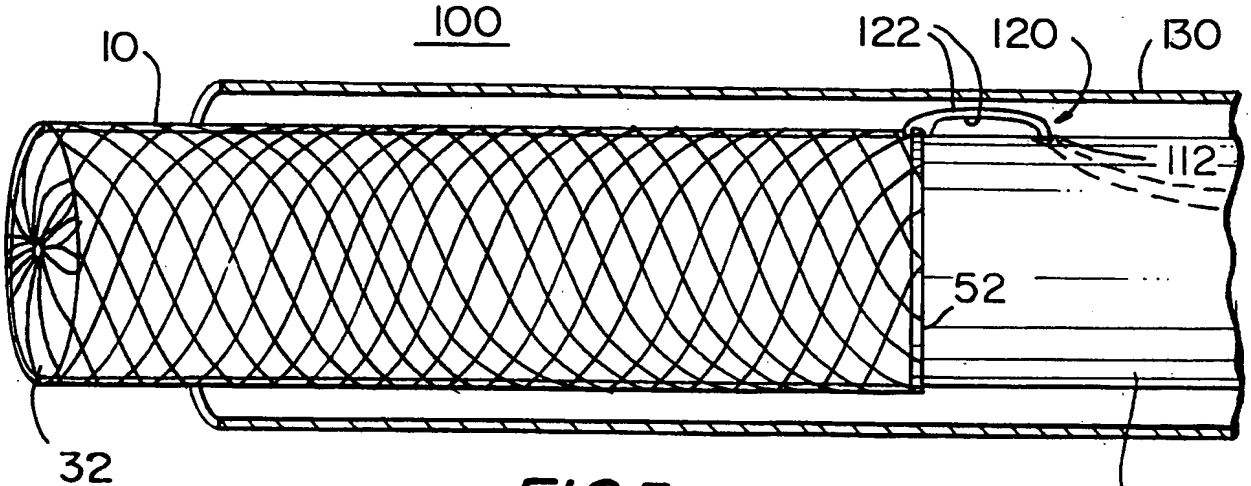

FIG.3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/06168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 108 420 A (MARKS LLOYD A) 28 April 1992	1-5, 8-17, 36-52
A	see column 3, line 3 - column 4, line 57; figures 1,2,5	18

X	EP 0 737 452 A (PULNEV SERGEI APPOLONOVICH ;KAREV ANDREI VLADIMIROVICH (RU); SCHUK) 16 October 1996	1,2,8-14
A	see column 7, line 5 - line 15	6,18,36, 44

A	US 5 578 045 A (DAS GLADWIN S) 26 November 1996	15
	see column 5, line 10 - line 39	
	see column 7, line 10 - line 14	

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 June 1998	18.06.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gérard, B

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

I. .ational Application No
PCT/US 98/06168

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication.where appropriate. of the relevant passages	Relevant to claim No.
A	US 5 258 000 A (GIANTURCO CESARE) 2 November 1993 see column 5, line 22 - line 33	1,5,46
P,X	WO 97 42878 A (AGA MEDICAL CORP) 20 November 1997	1,2,8-14
A	see page 10, line 18 - line 29 see page 29, line 29 - line 30 see page 27, line 14 - line 24; figures 16-18	3,6,18, 44
P,A	WO 98 02100 A (ANSON MEDICAL LTD ;ANSON ANTHONY WALTER (GB); PHILLIPS PETER WILLI) 22 January 1998 see claim 20	18

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/06168

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 27-35
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-17 and 18 - 26

   Plug with particular shape, and method of manufacturing

2. Claims: 36 - 43

   Delivery means for installing an elastic plug

3. Claims: 44 - 52

   Plug composed of two associated elastic materials to build a frame a web

INTERNATIONAL SEARCH REPORT

Information on patent family members

Ir ational Application No
PCT/US 98/06168

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